

Hippocratic oath and conversion of ethico-regulatory aspects onto doctors as a physician, private individual and a clinical investigator

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ABSTRACT

Hippocratic Oath is a living document for ethical conduct of the physicians around the world. World Medical Association has been amending the oath as per the contemporary times. Although physicians maintain their ethical standards while treating a patient yet many a times social, administrative and ruling powers either use physicians as their tool of oppression or victimize them for conducting duties as per their oath. The Tuskegee Syphilis Study and Human Radiation Experiments in America, Nazi Experiments in Germany and compulsory sterilization program in India were the studies where States used physicians for the advancement of their rationality or belief. Conversely victimization of physicians in Kosovo, Sri Lanka and incarcerating physicians for treating human immunodeficiency virus/acquired immunodeficiency syndrome patients in some countries is concerning. The Nuremberg code, the Declaration of Geneva, Belmont Report and Declaration of Helsinki are ethical documents while active involvement of Food and Drug Administration through “common rule” resulted in guidelines like International Conference on Harmonization and Good Clinical Practices. Still unethical studies are found in developing countries. Studies such as experimental anticancer drugs in 24 cancer patients without adequate prior animal testing and informed consent in Kerala, studies at All India Institute of Medical Sciences in New Delhi resulted in 49 deaths of children and many more suspicious studies are rampant. Reverting back to the fundamentals of the medical profession; teaching medical ethics and enforcement of “medical neutrality” by embarking some grade of “medical immunity” on the basis of the oath is necessary for ethical conduct of physicians.

Key Words: Ethical documents, hippocratic oath, medical ethics, medical immunity, medical neutrality

INTRODUCTION

Medical practitioners under oath who follow medical ethics must understand the word Ethics and derivation of its principles in medical practice over a period of time. Ethics refers to moral principles that control or influence a person's behavior whereas “ethical” means connected with beliefs and principles about what is right and wrong.^[1] Origin of the word Ethics is from the Greek word “ethos” meaning custom or character. It exudes from within a person, imparts a value system distinguishing rights from the wrongs and build after imbibing values achieved from

parents, religion, culture, society, faith and other influences. The principles of medical ethics have been penned down by many great physicians that affect every aspect of the medical professionals including their role as a physician as a private individual and as a clinical investigator.

DOCTORS AS A PHYSICIAN

It is quite obvious that out of these principles Hippocratic Oath [Table 1] is the most revered one. That is an

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Table 1: Original oath translated by Michael North, national library of medicine, 2002^[3]**Hippocratic oath**

I swear by Apollo the physician and Asclepius and Hygieia and Panacea and all the gods and goddesses as my witnesses, that, according to my ability and judgment, I will keep this oath and this contract

To hold him who taught me this art equally dear to me as my parents, to be a partner in life with him and to fulfill his needs when required; to look upon his offspring as equals to my own siblings and to teach them this art, if they shall wish to learn it, without fee or contract; and that by the set rules, lecture and every other mode of instruction, I will impart a knowledge of the art to my own sons and those of my teachers and to students bound by this contract and having sworn this oath to the law of medicine, but to no others

I will use those dietary regimens which will benefit my patients according to my greatest ability and judgment, I will do no harm or injustice to them

I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan; and similarly I will not give a woman a pessary to cause an abortion

In purity and according to a divine law I will carry out my life and my art I will not use the knife, even upon those suffering from stones, but I will leave this to those who are trained in this craft

Into whatever homes I go, I will enter them for the benefit of the sick, avoiding any voluntary act of impropriety or corruption, including the seduction of women or men, whether they are free men or slaves

Whatever I see or hear in the lives of my patients, whether in connection of my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private

So long as I maintain this oath faithfully and without corruption, may it be granted to me to partake of life fully and the practice of my art, gaining the respect for all men for all time. However, should I transgress this oath and violate it, may the opposite be my fate

old (460-377 BC), honored and living “ethical code” for physicians and a binding document for their conduct.^[2,3] Its relevance has been increasing over the time especially in conflict areas of the world. The aftermath of the biggest conflict of the present century, i.e., World War II (WW2), revealed the reciprocal vulnerability of the doctors in a changing socio-administrative milieu. Moreover, the most famous trial of the physicians of the Nazi era for their atrocities on the minority was not held on the basis of then existing rules and laws of the Germany, but on the basis of Hippocratic Oath.^[4] That implies that the professional ethical duties of doctors stand above the ruling powers and laws of the land. Most of the time oath takers are victimized for pursuing their duties as per their binding document. Recently, we witnessed that physicians had been killed in artillery attacks on hospitals and detained by the government in Sri Lanka in 2009^[5] for treating the perceived adversaries of the state. The 34 Kosovar Albanian physicians were detained, tortured and killed extra-judicially by Serbian forces in conflict areas.^[6] Treating patients of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS)

may be considered a crime in some part of the world due to conflicting perception of the State and dilemma of the physicians in case of Intra or Intergenerational assisted reproduction has put another ethical dimension in exercising their duties.

DOCTORS AS A PRIVATE INDIVIDUAL

Despite the original Hippocratic Oath in its second paragraph denouncing the charging and fee taking culture in medical education and considering charging fee as a roadblock in delivering a free and fair health-care. The emerging issue that has infested the medical fraternity, now, is the commercialization of medical education and services. The large scale privatization of medical education in many countries has resulted in the lot of investment and expenditure in getting MBBS and a specialization degree. This creates an inherent individual self-interest in recovering the investment by unnecessary means of creating liaisons with pharmaceutical companies, diagnostic laboratories and charging the patients.

DOCTORS AS A CLINICAL INVESTIGATOR

By virtue of Hippocratic Oath all the physicians of the world are congregated into one global ethical community. However, their voices are not always shared as we find only few contributions on medical ethics discussion in the international medical literature from authors of developing countries.^[7] Especially from India which is the hotbed for clinical trials activities as much as 20-30% of the global share.^[8] There are many unethical clinical trials in India without any regulatory approval such as with Letrozole in 430 women for ovulation, customized erythromycin vaginal pellets in 790 impoverished women and an anticancer drug without any preclinical animal studies administered to 24 patients in Kerala.^[9] This led John Hopkins University to make a conclusion that drugs with inadequate animal testing are being used in patients with inadequate informed consent and thus clinical investigators use patients as guinea pigs in them.^[10]

Revisit and proper understanding of the Hippocratic Oath is very necessary in the light of present issues of ethical malpractices throughout the world. Consequently, Hippocratic tradition progression in the form of Modern version of oath by World Medical Association [Table 2] has shifted the benevolent paternalism of physicians toward empowerment of patients' decision making in Clinical Care and their rights in Clinical Research.^[11,12] This drastic change of authority of decision making has led to the utmost consideration of values, preferences and decision making of the treating subjects.^[12] Therefore, now there is a consensus in many parts of the world to teach medical

Table 2: Duties of Physicians adopted by the 3rd general assembly of the world medical association, London, England, october 1949 latest updated on 57th WMA general assembly, Pilanesberg, South Africa, october 2006^[11]

Duties of physicians in general

A physician shall

- Always exercise his/her independent professional judgment and maintain the highest standards of professional conduct
- Respect a competent patient's right to accept or refuse treatment
- Not allow his/her judgment to be influenced by personal profit or unfair discrimination
- Be dedicated to providing competent medical service in full professional and moral independence, with compassion and respect for human dignity
- Deal honestly with patients and colleagues and report to the appropriate authorities those physicians who practice unethically or incompetently or who engage in fraud or deception
- Not receive any financial benefits or other incentives solely for referring patients or prescribing specific products
- Respect the rights and preferences of patients, colleagues and other health professionals
- Recognize his/her important role in educating the public but should use due caution in divulging discoveries or new techniques or treatment through non-professional channels
- Certify only that which he/she has personally verified
- Strive to use health care resources in the best way to benefit patients and their community
- Seek appropriate care and attention if he/she suffers from mental or physical illness
- Respect the local and national codes of ethics

Duties of physicians to patients

A physician shall

- Always bear in mind the obligation to respect human life
- Act in the patient's best interest when providing medical care
- Owe his/her patients complete loyalty and all the scientific resources available to him/her. Whenever an examination or treatment is beyond the physician's capacity, he/she should consult with or refer to another physician who has the necessary ability
- Respect a patient's right to confidentiality. It is ethical to disclose confidential information when the patient consents to it or when there is a real and imminent threat of harm to the patient or to others and this threat can be only removed by a breach of confidentiality
- Give emergency care as a humanitarian duty unless he/she is assured that others are willing and able to give such care
- In situations when he/she is acting for a third party, ensure that the patient has full knowledge of that situation
- Not enter into a sexual relationship with his/her current patient or into any other abusive or exploitative relationship

Duties of physicians to colleagues

A physician shall

- Behave toward colleagues as he/she would have them behave toward him/her
- Not undermine the patient-physician relationship of colleagues in order to attract patients
- When medically necessary, communicate with colleagues who are involved in the care of the same patient. This communication should respect patient confidentiality and be confined to necessary information

ethics in graduate courses for high standards of personal and professional values and that the knowledge of the ethical and legal aspects of medicine is important for comprehensive health-care.^[13] The current understanding of ethics in clinical care is the outcome of horrifying tragedies suffered by the mankind.^[14]

HISTORICAL PERSPECTIVE

The dilemma of present medical practice is that the ethical principles for patient care, education and consent cannot be understood without the historical context of those horrifying tragedies^[15] as Winston Churchill put it once "Those that fail to learn from history are doomed to repeat it". Moreover, doctors are even more vulnerable to fall in the hands of corrupt political and administrative regimes of the state.^[12] Nazi experiments were the notorious highlight for the professional misconduct under a dictatorial regime.

There were many inhuman clinical trials on the Jews in WW2 like placing people in vacuum chambers to determine the high altitude effects of low pressure and oxygen and placing people in ice water for days without any food.^[16] Experiments like sacrificing one of the twin brother or sister to compare the normal anatomy with the other where disease was induced to study the etiopathogenesis of natural history of the disease after autopsy of the dead one.^[17]

The 20 German physicians convicted by American forces after WW2 asked the judiciary to try them on the basis of existing guidelines in their country "Guidelines for Human Experimentation of 1931," first of their kind, but this did not happen as The chief Prosecutor Brig. Gen Telford Taylor in his opening statement said that the defendant had violated the fundamental principle of Hippocratic Oath "Primum non nocere."^[4] "The Nuremberg Code"^[18] was framed and they were put on trial on four counts: (1) The common design or conspiracy, (2) war crimes, (3) crimes against humanity and (4) membership in a criminal organization.^[4,18]

It is not that doctors of the conflict zone become the tool of oppression in the hands of autocratic powers to conduct inhuman studies. Rather, a more stable society like United States of America had also been involved in violation of even the basic human rights. That is why it becomes imperative on every physician to read the new version of Hippocratic Oath and Declaration of Helsinki as these are the living ethical documents.^[19]

The Tuskegee Syphilis Study^[20] was started in 1932 as a 6 months study, even before the Nazi Experiments were conducted, by the United States Public Health Service department to study the natural history of Syphilis in

around 400 black participants in Alabama, United States of America. The participants were given the impression that Government is giving them the free health-care, making it one of the earliest cases of “therapeutic misconception.” It was neither conveyed to them what the disease is, nor treated with the penicillin, though the cure was widely available in 1951, nor stopped even when the “declaration of Helsinki”^[21] was adopted in 1964. It was stopped when news published in the newspaper in New York Times in 1972 and treatment was given to the survivors in 1973, that is, almost 30 years after the Nazi Experiments.

The Willowbrook Viral Hepatitis study,^[22] Obedience to Authority Study (Milgram Study)^[23] and Monster Study^[24] were the other horrifying studies. In first mentally challenged children were fed with the stool extract infected with hepatitis virus and later on, injected with purified viral preparations and were refused admission in institution meant for mentally retarded children if parents did not consented to the study, second study involved the administration of 450 v currents to the participants by deception to replicate the psychological affliction to obey orders and in third, 22 orphan children were put under tremendous negative psychological stress to convert their normal speech into stuttering.

Beecher, professor at Harvard University, reported in New England Journal of Medicine in 1966, about 22 out of 50 such unethical studies, which were being conducted in America like to determine whether central Nervous system or cardiovascular system would collapse first. It was carried out by reducing blood pressure of the participants from the mean of 109 mmHg to mean of 48 mmHg without even considering the hypoxic damage of the brain post experimentation; giving high diet of nitrogen to generate hepatic encephalopathy in patients of cirrhosis of liver; and patients with minor surgeries put under cyclopropane anesthesia monitored for development of cardiac arrhythmias with different concentrations of Carbon dioxide injected in closed respiratory system by endotracheal intubation.^[25]

After president Bill Clinton formed the Advisory committee on “human radiation experiments” in 1994, it was revealed that US government had intentionally released radiation on many occasions from 1944 to 1974 and injected Plutonium in unaware subjects to see the effects of the atomic bomb on the people.^[26] Many incidents of medical intervention were done by the doctors under coercion by the states in many of countries like “forced vasectomy” or also known as compulsory sterilization to reduce the growing human population specially that of minority community. It was aggressively followed in India where many coercive tactics were used by the Government during the 19 months

of excesses of Emergency from 1976 to 1977^[27] where approximately 8 million vasectomies were done which was total 4 times that of previous years and 8 times that of the period before that.^[28] The weaknesses of the studies such as Women’s Health Initiative hormone trials,^[29] Death of Ellen Roche^[30] and 49 deaths of babies in All India Institute of Medical Sciences (AIIMS)^[31] have raised the concern of in competency of Institutional Review Board (IRB) and Independent Ethics Committee (IEC). Ellen Roche, an employee of the John Hopkins Asthma and Allergy Centre, was enrolled in the study of the same institute for inducing asthma by “hexamethonium” though it was not approved by Food and Drug Administration (FDA) as medication. Yet both National Institute of Health and the IRB had approved the study and she died. It came to light that Pediatrics department of AIIMS, India, vigorously conducted 42 sets of trials in 2½ years since January 1, 2006, to August 2008 where 49 babies died. It was seen that children of the poor families were kept for a long time in the hospital and the hospital, in reply to a query, justified that trials were conducted after clearance from their own ethics committee, the health ministry steering committee on ethics and the national ethics committee of Indian Council of Medical Research and Department of Biotechnology.

ETHICAL DOCUMENTS

Almost all hospitals have physicians as part of the ethical committees. The practice of evidence based medicine and ethical conduct demands understanding of ethical and legal issues of the present time. The physicians maintain their conduct to the highest standards from the time of antiquity on the basis of dynamic changes in the Hippocratic Oath wherein modern time has seen huge scientific and social changes. The original version of the oath was lacking many newer issues such as different professional aspect of medical specialization, privacy of the patients and doctors’ societal and legal responsibilities. The World Medical Association in its 2nd general assembly modernized the oath in Declaration of Geneva in 1948 and the latest version was modified in 2006 in its 57th General Assembly in South Africa to incorporate the changing aspects of medicine [Table 3].^[32]

The “Nuremberg code” was another milestone in Ethical documents for physicians after the conviction of Nazi doctors and it was built as regulatory guidelines for all the physicians of the world. Furthermore, it never got the acceptance for ethical conduct in the western world. The “declaration of Helsinki” was adopted in 1964 as the extension of Nuremberg code. Many new aspects were added in the Declaration where concept of legal guardianship was added for the consent for participation in clinical research in cases of legal incapacity. It also brought

Table 3: Oath adopted by the 2nd General Assembly of the WMA, Geneva, Switzerland, September 1948 latest updated on the 173rd WMA Council Session, Divonne-les-Bains, France, May 2006^[32]

At the time of being admitted as a member of the medical profession

I solemnly pledge to consecrate my life to the service of humanity
 I will give to my teachers the respect and gratitude that is their due
 I will practice my profession with conscience and dignity
 The health of my patient will be my first consideration
 I will respect the secrets that are confided in me, even after the patient has died
 I will maintain by all the means in my power, the honor and the noble traditions of the medical profession
 My colleagues will be my sisters and brothers
 I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient
 I will maintain the utmost respect for human life
 I will not use my medical knowledge to violate human rights and civil liberties, even under threat
 I make these promises solemnly, freely and upon my honor

WMA: World Medical Association

the concept of reviewing the research protocols by the independent committees.

Although Declaration of Helsinki became the most important milestone for the ethical conduct of the physician, but, it was ignored in major developed countries like USA where Tuskegee Syphilis Study compelled the parliament to pass an Act in 1974, creating a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission produced a report called “Belmont report”^[33] on the basis of principles of medical ethics introduced by Beauchamp and Childress in 1979^[34] for the ethical treatment of human subjects that includes three major concepts. One is “respect for person,” second “beneficence” and third was the “justice.” The Belmont report became the reference document for IEC/IRB.

REGULATORY OUTCOMES

Controlling the chain reactions started by distancing physicians from the basic tenants of Hippocratic Oath requires regulatory noose on clinical investigators. The regulation in the Clinical care and research all over the world follows the changes in FDA of USA,^[35] which was enacted in 1906 as Pure Food and Drug Act basically to regulate the inter-state trade of misbranded and adulterated foods, drinks and drugs. The physicians were unaware of the adulteration of drugs and thus, a great tragedy occurred in 1938 in which almost 107 people died due

to prescription of “Elixir Sulfanilamide” containing toxic ingredient “diethylene glycol,” which is used as anti-freeze in biofuel.^[36,37] The act was revised to Food, Drug and Cosmetic Act and it required a manufacturer to prove the safety of a drug before it could be marketed and later in 1962, when Kefauver-Harris Drug Amendments^[37] was added after “thalidomide disaster” when a sedative drug thalidomide caused the seal like limb deformity (Phocomelia) in newborn babies and the “cutter incidents”^[38] in 1955 where 40,000 children develop abortive polio, 51 permanently paralyzed, 10 died, including family members, after receiving vaccine containing live polio virus. The National research act of 1974 in USA also established the “common rule”^[39] to protect the vulnerable subjects. These Codes of Federal Regulations control Pharmaceutical industry research through FDA. Although Clinical Research became very well-regulated affair in developed countries but developing countries were lacking the initiatives to frame the regulatory guidelines.

In 1982, a non-governmental organization, The Council for International Organization of Medical Sciences collaborated with the World Health Organization (WHO) and United Nations to translate the “declaration of Helsinki” into regulatory guide document for third world countries. It proposed “International Ethical Guidelines for Biomedical Research” involving human subjects later updated in 2002^[40] when a controversy occurred in Africa about the intervention in treating HIV/AIDS patients for not maintaining “clinical equipoise.” Later on it was seen that every country operates in a different set of technical and administrative milieu and even with extra and unnecessary efforts it was difficult to get the approval of redundant technical requirements therein.

The European Federation of Pharmaceutical Industries and Associations in 1990 arranged a meeting for regulatory and industry representative from USA, Japan and Europe to “harmonize” the regulatory requirements, overcoming the country specific hurdles. These meetings resulted in guidelines called “International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use.”^[41] The most important outcome of these guidelines was the creation of “the Guidelines for Good Clinical Practices (GCP)” in 1996 containing, definitions of technical terms such as blinding, protocol and randomization, principles of GCP, vulnerable subjects, section of IRB including Informed Consent and distinction between IRB and IEC.

It is now being appreciated that legal, ethical and regulatory knowledge is essential for every practicing doctor to become a clinical investigator and simultaneously providing evidence based comprehensive therapy. Teaching of Ethics and

Regulation is important for medical graduates in the present scenario. Oath bearers should be the trainers of oath takers to inculcate the professional ethics for right, safety and well-being of the patients throughout the teachings of medical graduates. Furthermore, it is imperative to involve the oath bearers for teaching the ethics, conducts the clinical research and become part of the various ethical and regulatory bodies. It will reduce difficulties faced by surrendering clinical research to people who are not oath-takers, do not care for patients and have little knowledge of conducting clinical trials.^[42] Ethics of Clinical Care and Clinical Research are different and negates the very purpose of patient care if doctor views every patient as a potential subject as it violates the physicians' duty to provide most appropriate treatment.

In our opinion, contemporary churning phases of human lives all over the world where no one knows how many physicians are being compelled by the autocratic regime to do the anti-Hippocratic activities, some grade of "Medical Immunity" to oath takers should be there as a "Global community beyond the boundary of states." It should be at par like diplomatic immunity given to diplomats, to protect and maintain the medical neutrality affected by the political gains. Remedy of ethical malpractices, ameliorating conflict with the individual self-interest, maintaining medical neutrality and providing compassionate patient care can only happen if every physician trained on the basis of no-profit no-loss philosophy. Therefore rationing of health-care including training of medical professionals, empowerment of physicians as an autonomous entity related to the deliverance of their duty and adherence to their oath is paramount for their free and transparent obligation.

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